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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 319

[Docket No. APHIS-2011-0132]

RIN 0579-AD62

Importation of Fresh Apricots From Continental Spain

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the fruits and vegetables regulations to allow the importation into the United States of fresh apricots from continental Spain (excluding the Balearic Islands and Canary Islands). As a condition of entry, fresh apricots from continental Spain will have to be produced in accordance with a systems approach that includes registration of production locations and packinghouses, pest monitoring, sanitary practices, chemical and biological controls, and phytosanitary treatment. The fruit will have to be imported in commercial consignments, with each consignment identified throughout its movement from place of production to port of entry in the United States. Consignments will have to be accompanied by a phytosanitary certificate issued by the national plant protection organization of Spain certifying that the fruit is free from all quarantine pests and has been produced in accordance with the systems approach. This action will allow for the importation of fresh apricots from continental Spain while continuing to protect against the introduction of plant pests into the United States. EFFECTIVE DATE: [Insert date 30 days after date of publication in the Federal Register].

FOR FURTHER INFORMATION CONTACT: Ms. Meredith C. Jones, Senior Regulatory Policy Specialist, Regulatory Coordination and Compliance, PPQ, APHIS, 4700 River Road Unit 156, Riverdale, MD 20737-1231; (301) 851-2018.

SUPPLEMENTARY INFORMATION:

Background

The regulations in "Subpart–Fruits and Vegetables" (7 CFR 319.56-1 through 319.56-62, referred to below as the regulations) prohibit or restrict the importation of fruits and vegetables into the United States from certain parts of the world to prevent the introduction and dissemination of plant pests within the United States.

On January 30, 2013, we published in the Federal Register (78 FR 6227-6232, Docket No. APHIS-2011-0132) a proposal¹ to amend the regulations concerning the importation of fruits and vegetables to allow the importation of fresh apricots (Prunus armeniaca L.)² from continental Spain (excluding the Balearic Islands and Canary Islands) into the United States. We proposed to allow the importation of fresh apricots from continental Spain only if they were produced in accordance with a systems approach jointly agreed upon in a bilateral workplan between the Animal and Plant Health Inspection Service (APHIS) and the national plant protection organization (NPPO) of Spain. The systems approach addresses four quarantine pests that the pest risk analysis (PRA) determined could follow the pathway of consignments of fresh apricots imported from continental Spain into the United States:

• The Mediterranean fruit fly (Medfly), Ceratitis capitata Wiedemann,

¹To view the proposed rule, supporting documents, and the comments we received, go to http://www.regulations.gov/#!docketDetail;D=APHIS-2011-0132.

²Although we included <u>Prunus armeniaca</u> Marshall as the scientific name for apricot in the proposed rule and risk assessment, both that name and <u>Prunus armeniaca</u> L. refer to the same species.

- The plum fruit moth, Cydia funebrana (Treitschke),
- Leaf scorch, Apiognomonia erythrostoma (Pers.), a fungus, and
- Brown rot, Monilinia fructigena Honey, a fungus.

The proposed systems approach included the following requirements: Registration of production locations and packinghouses; pest monitoring and control, including trapping for C. funebrana and C. capitata to demonstrate areas of low prevalence; grove sanitation; chemical controls; inspection by the NPPO of Spain for quarantine pests; and phytosanitary treatment in accordance with 7 CFR part 305 and the Plant Protection and Quarantine (PPQ) Treatment Manual.³ We also proposed that fruit would have to be imported in commercial consignments, with each consignment identified throughout its movement from place of production to port of entry in the United States, and that consignments would have to be accompanied by a phytosanitary certificate issued by the NPPO of Spain stating that the fruit is free from all pests of quarantine concern and has been produced in accordance with the systems approach.

We solicited comments concerning our proposal for 60 days ending April 1, 2013. We reopened and extended the deadline for comments until June 13, 2013, in a document published in the <u>Federal Register</u> on May 29, 2013 (78 FR 32184, Docket No. APHIS-2011-0132). We received four comments by that date. They were from a foreign government, a State department of agriculture, an organization representing State plant regulatory agencies, and a university professor. They are discussed below by topic.

³http://www.aphis.usda.gov/import export/plants/manuals/ports/downloads/treatment.pdf.

General Comments

One commenter stated that we should not allow the import of apricots from Spain that have been sprayed with pesticides, unless methods can be devised to ensure that such fruit will not be toxic to consumers.

The U. S. Environmental Protection Agency (EPA) is responsible for registering pesticides for use in the United States. EPA also has the responsibility to establish limits, or tolerances, for pesticide residues in both raw agricultural commodities and processed foods; these tolerances apply to both imported and domestically grown foods. EPA-established tolerances are commodity specific and represent the maximum amount of pesticide residue that may legally remain in food. In the absence of a tolerance, any level of pesticide residue is prohibited. The U. S. Food and Drug Administration is responsible for enforcing EPA pesticide residue tolerances and for determining whether an imported food violates the Federal Food, Drug, and Cosmetic Act.

The proposed rule identifies the NPPO of Spain as the body responsible for conducting and supervising inspections, monitoring, trapping, surveying, and other activities required in the systems approach.

A commenter acknowledged that the NPPO of Spain is responsible for these activities but noted that there are other bodies and stakeholders involved, such as the Spanish Autonomous Communities (the first-level political and administrative divisions in Spain), auditing companies, integrated pest management associations, and field technicians and advisors. Their roles are defined by Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009, which established a framework for European Union (EU) action to achieve the sustainable

use of pesticides. The commenter stated that the responsibilities of each partner should be specified in future workplans under the proposed rules.

In all APHIS fruit and vegetable importation programs, the NPPO certifies that it is taking responsibility to ensure that these other involved parties act under NPPO direction and perform the actions required by the regulations and workplan. Moreover, the NPPO is the official participant in the International Plant Protection Convention, which establishes the reciprocal obligations that trading countries have to each other. Whether the NPPO fulfills its duties through other parties whose roles are described in European Community (EC) directives or through other means is an internal matter not subject to our regulations. If the NPPO of Spain desires, workplans for the apricot program can include information about which entities will perform which required actions, but in the event of failure to perform any required action APHIS will hold only the NPPO responsible for correcting the problems. We note that the cited EC directive addresses only pesticide use and integrated pest management, rather than systems approaches for the growth and certification of crops for export, and even within that scope the directive emphasizes in many places the responsibility of competent authorities in the Member State to ensure required actions are taken.

One commenter recommended that the bilateral workplan track closely with the pest mitigation measures specified by APHIS in the systems approach.

That will be the case. The bilateral workplan is based on the regulations but specifies the pest mitigation measures of the systems approach in greater detail.

We stated in the preamble to the proposed rule that, as a condition of entry, apricots from Spain would have to be produced in accordance with a limited harvest period and treated with surface disinfectant.

One commenter noted that neither of these mitigation measures appears in the proposed regulatory language for the systems approach and asked that we remove these measures.

The commenter is correct. These mitigation measures are not intended to be part of the systems approach and are not included in this final rule.

Monitoring and Oversight

We proposed in § 319.56-58(c)⁴ the requirement that the NPPO of Spain would have to visit and inspect places of production monthly, starting 2 months (60 days) before harvest and continuing until the end of the shipping season to verify that growers are complying with the proposed requirements.

One commenter stated that, given the ripening period of apricot is approximately May 1 through July 15, official inspections would have to be conducted from March to August, which under the proposed regulations would require six inspections. The commenter stated that six inspections are unnecessary and not cost-effective and suggested instead that the NPPO visit production sites once at the beginning of the export season, once during harvest, and at any other times the NPPO finds necessary to verify compliance. The commenter stated that throughout harvest the NPPO, the Autonomous Communities, and the auditing companies employed by them would control, evaluate, and validate field notebooks maintained by growers and inspection reports from field technicians or advisors. The commenter added that the NPPO of Spain would ensure that APHIS requirements are being fulfilled by the involved parties.

APHIS is making two changes in response to this comment. It is essential that the NPPO effectively monitor compliance before and during harvest to identify and prevent pest risks.

⁴ The provisions of the systems approach will be added to the regulations as § 319.56-63. In this final rule, we discuss the comments in terms of provisions of proposed § 319.56-58 so that the reader can follow along with the proposal.

However, effective inspection does not necessarily require six visits each year, and depending on the personnel authorized by the NPPO to conduct various compliance monitoring activities, it may not be necessary that NPPO employees visit each production site each month. While it is important that the production site be inspected prior to harvest, both to look for early signs of pests that may not be as visible later and to familiarize the inspector with the production area, upon further consideration we believe a reasonable standard is that a pre-harvest inspection occur at least 1 month prior to harvest rather than the proposed 2 months. Therefore, we are changing the proposed standard to read "starting at least 1 month before harvest." We note also that the term "before harvest" refers to the harvest as conducted at each place of production, not to the harvest season in general, which in some cases could result in fewer inspections being necessary.

As noted above, production site inspections are the responsibility of the NPPO and must be done under NPPO direction to verify the conditions and actions required by the regulations and workplan. However, we acknowledge that the identity of the personnel authorized to conduct inspection-related activities may be determined by the NPPO and specified in the workplan, and that in some cases the NPPO may authorize other personnel, such as employees of an Autonomous Community or an auditing company, to perform duties related to inspection. If so, these personnel must be accountable to the NPPO. Therefore, in this final rule we are changing the relevant sentence in § 319.56-58(c)(1) to read "The NPPO of Spain, or an authorized person designated in the workplan, must visit and inspect...".

We proposed to require in § 319.56-58(c)(1) that any personnel conducting trapping and pest surveys in accordance with the systems approach be hired, trained, and supervised by the NPPO of Spain.

The same commenter noted that, while under EU regulations the NPPO of Spain is responsible for ensuring that such personnel are appropriately trained, such personnel are not necessarily hired or trained by the NPPO of Spain. The commenter asked that we delete the words "hired" and "trained" from this requirement.

As we noted above, we understand that in some cases the NPPO may authorize other personnel not hired or trained by the NPPO, such as employees of an Autonomous Community or an auditing company, to perform duties related to inspection under the supervision of the NPPO. However, we agree that they do not necessarily have to be hired or trained by the NPPO. Therefore, we are deleting the words "hired" and "trained" from the proposed requirement in § 319.56-58(c)(1) and replacing those words with the term "accredited" to indicate they have been determined by the NPPO to be qualified to perform the assigned duties.

Two commenters stated that procedures should be in place to confirm that approved treatments are applied properly to fresh apricot fruit imported from continental Spain.

Under the bilateral workplan, APHIS will confirm that treatments of fresh apricot fruit are properly applied under supervision of the NPPO of Spain in accordance with the cold treatment regulations in § 305.6 and the PPQ Treatment Manual. Furthermore, under § 319.56-58(c)(4), the NPPO of Spain will be required to retain all forms and documentation related to export program activities, including approved treatments, in places of production and packinghouses for at least 1 year and, upon request, provide them to APHIS for review.

Mitigations for A. erythrostoma

One commenter noted that the PRA identifies the fungus <u>A</u>. <u>erythrostoma</u> as a pest that could follow the pathway of consignments of fresh apricots imported from Spain to the United

States. The commenter stated, however, that scientific literature⁵ identifies <u>A</u>. <u>erythrostoma</u> as being only a pest of cherry in Spain, and consequently the mitigation measures we proposed for <u>A</u>. <u>erythrostoma</u> in fresh apricot are not supported by the literature.

We reviewed the documents cited by the commenter to support that <u>A</u>. <u>erythrostoma</u> does not occur on apricot in Spain. None of the documents rules out <u>A</u>. <u>erythrostoma</u> as being a potential pest risk to apricot in Spain, and one of the documents (Santiago, 2008) acknowledged that apricots are in fact a host of the pathogen. Moreover, <u>A</u>. <u>erythrostoma</u> has been reported as an apricot pest in Italy, Bulgaria, and Austria, and is listed as an apricot pest in the 2004 European and Mediterranean Plant Protection Organization standard "Good Plant Protection Practices for Stone Fruits."

If a plant pest of quarantine concern is reported on a commodity in a particular country, APHIS considers it to be an import risk for all potential hosts of that pest in that country, unless there are mitigations in place to prevent its spread. No pest-free or low-prevalence areas for A. erythrostoma have been established in Spain, leading to the risk that apricot production could be affected by the pathogen if the proposed mitigations are not applied. Therefore, we are making no changes with regards to the mitigations we proposed to require for A. erythrostoma. Mitigations for C. funebrana

We proposed to require in § 319.56-58(f) that the NPPO of Spain use one of two mitigation options to address the risk potential posed by <u>C</u>. <u>funebrana</u>, the plum fruit moth,

⁵ Pérez JA, Garcia T, Arias A, Martínez de Velasco D. 1989. <u>Lucha contra el hongo del cerezo Gnomonia erythrostoma (Pers.) Auersw. I. Eficacia de materias activas. Boletín Sanidad Vegetal y Plagas 4: 315-321. Sánchez OL, Garcia MT. 2007. <u>Gnomonia. Apiognomonia erythrostoma. Fichas técnicas de Sanidad Vegetal. Ficha 10. Junta de Extremadura. Consejería de Agricultura y Desarrollo Rural. Dirección General de Explotaciones Agrarias. Santiago R. 2008. <u>Apiognomonia erythrostoma (Pers.) Höhnel. La "Gnomonia" del cerezo. Ficha 20. Laboratorio de Diagnostico del Servicio de Sanidad Vegetal. Junta de Extremadura.</u></u></u>

which we determined in the PRA to be one of the pests that could follow the pathway of apricot from Spain. Under the first mitigation option in § 319.56-58(f)(1), apricots would have to originate from an area designated as free of \underline{C} . funebrana in accordance with § 319.56-5. Under the second option in § 319.56-58(f)(2), apricots would have to originate from an area that has been demonstrated to have a low prevalence of \underline{C} . funebrana. The NPPO of Spain would be required to visit and visually inspect registered places of production during the growing season and harvest period for signs of \underline{C} . funebrana to demonstrate that the places of production have a low prevalence of \underline{C} . funebrana and to verify that the growers are complying with the mitigation measures required as part of the systems approach.

One commenter stated that, while the PRA identifies <u>C</u>. <u>funebrana</u> as a quarantine pest that could follow the pathway, its prevalence in apricots is much lower than that of the oriental fruit moth, <u>C</u>. <u>molesta</u>, and outbreaks of <u>C</u>. <u>funebrana</u> only take place occasionally in apricot orchards located near plum orchards. The commenter recommended that mitigation measures for <u>C</u>. <u>funebrana</u> such as pheromone trapping and monitoring should only be required for those apricot orchards located in the vicinity of plum orchards.

We have no evidence to suggest that outbreaks of <u>C</u>. <u>funebrana</u> only occur in apricot orchards that are located near plum orchards. At any rate, it would not be practical to find every apricot orchard located near a plum orchard and determine specific boundaries within which mitigations for <u>C</u>. <u>funebrana</u> would be required.

As part of the mitigations for establishing an area of low pest prevalence for C. <u>funebrana</u>, we proposed to require in § 319.56-58(f)(2) that the NPPO of Spain sample and visually inspect a quantity of fruit specified in the workplan. Specific inspection requirements would be included in the bilateral workplan and adjusted as necessary to ensure that inspection is hectares to be visually inspected by the NPPO of Spain every 7 days during the growing season. During the harvest period, samples of 40 fruits per tree from 50 trees within every 4 hectares would have to be visually inspected by the NPPO of Spain every 7 days until harvest is completed. If more than 1 percent of the fruits sampled in a week are damaged or found to have any life stage of C. funebrana, remedial measures would have to be implemented.

The same commenter opposed the requirement to increase the sampling size during the harvest period, stating that the symptoms of <u>C</u>. <u>funebrana</u> are more visible in the latter part of the growing season, thereby making infested fruit easier to detect. As support, the commenter cited APHIS pest response guidelines⁶ stating that <u>C</u>. <u>funebrana</u> larvae feed internally, resulting in internal symptoms only. Citing another study, ⁷ the commenter added that infested fruits may ripen faster than uninfested fruits, allowing them to be readily detectable. The commenter concluded that the biology of <u>C</u>. <u>funebrana</u> does not support increasing the sample size during harvest period from 1,000 to 2,000 fruits per 4 hectares each week and recommended that the sample size of 20 fruits per tree from 50 trees within every 4 hectares should remain invariable through the petal fall phase to the harvest period.

We are making no changes based on the comment. Contrary to the commenter's point, the APHIS pest response guidelines the commenter cited actually state that symptoms of infestation are readily visible on fruit early in the growing season. During the harvest season, the

⁶ USDA, APHIS, PPQ. 2011. New Pest Response Guidelines: Plum Fruit Moth (<u>Cydia funebrana</u>. Washington, DC: http://www.aphis.usda.gov/import_export/plants/manuals/online_manuals.shtml.

⁷ Vernon, JDR. 1971. <u>Observations on the biology and control of the plum fruit moth. Plant Pathology</u> 20(3): 106-110.

sample size must remain higher in order to minimize the risk of larvae being imported to the United States in infested fruit.

The same commenter stated that we did not specify in the proposed regulatory text a minimum amount of sampled fruit in relation to the area of the place of production and suggested that in accordance with current standards of integrated production we amend § 319.56-58(f)(2) to set a minimum of 50 trees per place of production.

The minimum amount of sampled fruit in relation to the area of the place of production will be worked out by APHIS in consultation with the NPPO of Spain. The sample amount will then be specified in the workplan required in § 319.56-58(a)(1). Specifying the sample size in the workplan rather than in the regulations will give us the flexibility to change the size to meet changing conditions.

Finally, the commenter stated that fruit is the primary sample unit and therefore the term "growing season" should be restricted to a more specific period such as "fruit setting" or "after petal fall."

Our use of the term "growing season" is compatible with the specific period suggested by the commenter, i.e., from fruit set through the end of harvest season.

Mitigations for C. capitata

We proposed to require in § 319.56-58(g)(1) that trapping for <u>C</u>. <u>capitata</u>, a fruit fly, be conducted in the places of production to demonstrate that those places have a low prevalence of <u>C</u>. <u>capitata</u>. If the prevalence rises above levels specified in the bilateral workplan, remedial measures approved jointly by APHIS and the NPPO of Spain would have to be implemented. We also proposed to require in § 319.56-58(g)(2) that all apricots for export from continental Spain to the United States be treated for <u>C</u>. <u>capitata</u> in accordance with 7 CFR part 305.

Referring to the trapping requirements we proposed for <u>C</u>. <u>capitata</u>, one commenter stated that the threshold of 0.5 flies per trap per day would not allow growers to meet the technical guidelines of integrated production and would have a negative impact on the environmental sustainability of the growing region. The commenter stated that in accordance with current technical standards of integrated production used in the Autonomous Communities of Spain, 2 flies per trap per day is a more accurate intervention threshold for <u>C</u>. <u>capitata</u>.

We are making no changes in response to the comment. \underline{C} . $\underline{capitata}$ is a serious quarantine pest that is not present in the United States, but is endemic to Spain. Accordingly, we require a high level of protection against the introduction of \underline{C} . $\underline{capitata}$. The threshold of 0.5 flies per trap per day is appropriate given apricot's host status to \underline{C} . $\underline{capitata}$ and is consistent with other import programs, such as the one for Spanish clementines.

We stated in the proposed rule that two phytosanitary mitigation measures for \underline{C} . capitata would be required because high larval populations in fruit can overwhelm the effectiveness of cold treatment. We noted that the trapping and field mitigation measures together would maintain populations of \underline{C} . capitata at acceptably low prevalence levels and ensure that cold treatment is effective.

One commenter asked to define what we mean by "high larval populations." The commenter stated that such language does not provide additional information or quantitative scientifically supported data and that it would be necessary to state whether those populations are related to a percentage of fruit infestation.

What APHIS determines to be high larval populations varies with the fruit in question and the prevalence of <u>C</u>. <u>capitata</u> in a particular area. Generally, high larval populations are those that pose a substantial risk of overwhelming pest mitigations that are in place. For

example, in 2001 high populations of <u>C</u>. <u>capitata</u> larvae were detected in imported Spanish clementines that had undergone cold treatment, some of which were alive upon arrival in the United States.

One commenter recommended that all treatments of fresh apricot fruit from continental Spain should be applied prior to importation into the United States.

Pest mitigation measures, including treatments approved by APHIS and the NPPO of Spain, are applied to the fruit prior to its importation to the United States. The phytosanitary certificate issued by the NPPO of Spain will also have to confirm that each consignment of apricot fruit has undergone cold treatment for <u>C</u>. <u>capitata</u>.

Post-Harvest Procedures and Packinghouse Requirements

In proposed § 319.56-58(i), we included the requirement that, during the time the packinghouse is used to pack and export apricot fruit to the United States, the packinghouse must only accept fruit from places of production registered and approved by the NPPO of Spain. We proposed to require the packinghouse to pack no fruit for other markets during the time it packs apricots produced in accordance with the proposed rule's systems approach.

One commenter suggested that we allow packinghouses to pack fruit for other markets during the same period, but under conditions that would prevent commingling of the fruit. The conditions they provided were 1) the packing lines in packinghouses be cleared prior to packing apricots for the United States, and 2) fruit destined for the United States must always be identified and stored separately from fruit destined for other markets. The commenter added that similar measures are already included in preclearance work plans for the export of sweet oranges, clementines, and other mandarins to the United States.

After careful consideration, we have decided to change the rule in response to this comment, according to the following reasoning. Consider the following scenario for apricots produced in accordance with the proposed rule. There are two areas of pest risk associated with the packinghouse. There is a small risk that C. capitata could enter the packinghouse associated with other articles destined for other markets, move to regulated apricots, and lay eggs in those apricots. However, this is unlikely because normal packinghouse operations make such movement of pests between lots exceedingly rare. There is a slightly larger risk that articles destined for other markets could become accidentally mixed with regulated apricots and shipped to the United States. Such mixing of articles could result in C. capitata larvae being shipped to the United States. We believe both of these areas of risk can be controlled using the methods suggested by the commenter. Maintaining the identity of regulated apricots at the packinghouse and ensuring separation between them and other articles are the key concerns. The proposed rule, in § 319.56–58(a)(4), states that regulated apricots must "remain identifiable when the fruit leaves the grove, at the packinghouse, and throughout the export process."

This identity requirement will aid achieving separation in the packinghouse. To fully achieve effective separation, we are changing the packinghouse requirement in § 319.56–58(i) to read as follows: "During the time registered packinghouses are in use for packing apricots for export to the United States in accordance with the requirements of this section, packing lines must be cleared of all other articles and plant debris prior to packing such apricots, and such apricots must be stored in a room separate from any other fruits or plant articles while the apricots are at the packinghouse."

Phytosanitary Inspection and Certificate

Two commenters stated that risk mitigation measures should include an additional high level of inspection by APHIS at the U.S. port of entry.

The risk mitigations we are adding to the regulations for the importation of fresh apricots from continental Spain include two points of inspection, one in continental Spain and one at the U.S. port of entry. Under § 319.56-58(j)(1), a biometric sample of apricots, jointly agreed upon by APHIS and the NPPO of Spain, will be required to be inspected in Spain by the NPPO following post-harvest processing. The sample will have to be visually inspected for the quarantine pests A. erythrostoma, C. funebrana, and M. fructigena, and a portion of the fruit cut open to inspect for the internal pest C. capitata. If any of these quarantine pests are found, the entire consignment of apricots will be prohibited from import into the United States. In addition, each lot of apricot fruit from continental Spain will have to be presented for inspection at the U.S. port of entry with an accompanying shipping document indicating the place of production and the packinghouse in which the fruit was processed. Each consignment of apricot fruit will have to be accompanied by a phytosanitary certificate issued by the NPPO of Spain stating that the fruit has been treated for C. capitata in accordance with 7 CFR part 305 and includes an additional declaration stating that the fruit in the consignment was inspected and found free from A. erythrostoma, C. capitata, C. funebrana, and M. fructigena.

One commenter stated that we should not suspend exports from the places of production if any <u>C</u>. <u>capitata</u> are detected in the required postharvest inspection of apricots in Spain. The commenter stated that a certain percentage of infestation should be accepted for apricots because they will be subjected to a cold treatment, which is the case in other operational workplans between Spain and the United States for the export of sweet oranges, clementines, and other

mandarins. The commenter also stated that the phytosanitary certificate should not be required to state that the consignment is free of \underline{C} . capitata.

We are making no changes based on this comment. Given the serious threat

C. capitata poses, we believe that it is reasonable to have no tolerance level for C. capitata
infestation and to stop accepting shipments from a place of production pending investigation
when a single larva is found during inspection. Furthermore, neither the operational workplan
nor the regulations for importation of sweet oranges, clementines, and mandarins from Spain
have such tolerances. We note that the relevant requirement in our regulations for the
importation of clementines from Spain, § 319.56-34(f), states that "If inspectors find a single live
Mediterranean fruit fly in any stage of development during an inspection, the entire consignment
of clementines will be rejected. If a live Mediterranean fruit fly in any stage of development is
found in any two lots of fruit from the same orchard during the same shipping season, that
orchard will be removed from the export program for the remainder of that shipping season."

The same commenter suggested a biometric sample size of 200 fruits for the post-harvest inspection of <u>C</u>. <u>capitata</u>. The commenter calculated that sample size using the standard in the International Standards For Phytosanitary Measures No. 31, "Methodologies for sampling of consignments" (International Plant Protection Convention, 2009). ⁸ The commenter stated that calculating the sample size for a 95 percent confidence level at a 2 percent level of detection, according to a 75 percent efficacy value where the lot size is large and sufficiently mixed, yields 199 or 200 fruits by the binomial or Poisson distribution, respectively.

We do not disagree with the commenter's methodology, but as we stated in the proposed rule, the actual sampling rate will be worked out by technical experts in APHIS in consultation

 $^{^{8}} https://www.ippc.int/file_uploaded/1229532867492_ISPM31_2008_E.pdf.$

with the NPPO of Spain. The sample size will then be specified in the workplan required in $\S 319.56-58(a)(1)$. Specifying the sample size in the workplan rather than in the regulations will give us the flexibility to raise or lower the fruit sampling rate when conditions indicate a higher or lower risk of \underline{C} . capitata infestation.

Therefore, for the reasons given in the proposed rule and in this document, we are adopting the proposed rule as a final rule, with the changes discussed in this document.

Executive Order 12866 and Regulatory Flexibility Act

This final rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

In accordance with the Regulatory Flexibility Act, we have analyzed the potential economic effects of this action on small entities. The analysis is summarized below. Copies of the full analysis are available by contacting the person listed under FOR FURTHER INFORMATION CONTACT or on the Regulations.gov Web site (see ADDRESSES above for instructions for accessing Regulations.gov).

This rule will amend the regulations to allow the importation into the United States of fresh apricots from continental Spain, subject to a systems approach.

The economic analysis examines impacts for U.S. small entities of a rule that would allow fresh apricot imports from continental Spain. Spain is expected to export at most 10 standard shipping containers of fresh apricot per year to the United States. Each container can hold approximately 18 metric tons (MT), thus fresh apricot imports from Spain may total as much as 180 MT annually. This amount is equivalent to about 1 percent of current U.S. consumption. With U.S. fresh apricot exports four times the quantity imported, and the amount

expected to be imported from Spain very small in comparison to current U.S. consumption, any market effects of such a relatively small change in supply would be minor.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

Executive Order 12988

This final rule allows fresh apricots to be imported into the United States from continental Spain. State and local laws and regulations regarding fresh apricots imported under this rule will be preempted while the fruit is in foreign commerce. Fresh fruits are generally imported for immediate distribution and sale to the consuming public, and remain in foreign commerce until sold to the ultimate consumer. The question of when foreign commerce ceases in other cases must be addressed on a case-by case basis. No retroactive effect will be given to this rule, and this rule will not require administrative proceedings before parties may file suit in court challenging this rule.

Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.), the information collection or recordkeeping requirements included in this final rule, which were filed under 0579-0402, have been submitted for approval to the Office of Management and Budget (OMB). When OMB notifies us of its decision, if approval is denied, we will publish a document in the <u>Federal Register</u> providing notice of what action we plan to take.

E-Government Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the E-Government Act to promote the use of the Internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes. For information pertinent to E-Government Act compliance related to this rule, please contact Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 851-2908.

List of Subjects in 7 CFR Part 319

Coffee, Cotton, Fruits, Imports, Logs, Nursery stock, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements, Rice, Vegetables.

Accordingly, we are amending 7 CFR part 319 as follows:

PART 319-FOREIGN QUARANTINE NOTICES

1. The authority citation for part 319 continues to read as follows:

Authority: 7 U.S.C. 450, 7701-7772, and 7781-7786; 21 U.S.C. 136 and 136a; 7 CFR 2.22, 2.80, and 371.3.

2. A new § 319.56-63 is added to read as follows:

§ 319.56-63 Fresh apricots from continental Spain.

Fresh apricots (<u>Prunus armeniaca</u> L.) may be imported into the United States from continental Spain (excluding the Balearic Islands and Canary Islands) only under the conditions described in this section. These conditions are designed to prevent the introduction of the following quarantine pests: <u>Apiognomonia erythrostoma</u> (Pers.), a brown rot fungus; <u>Ceratitis capitata</u> Wiedemann, the Mediterranean fruit fly; <u>Cydia funebrana</u> (Treitschke), the plum fruit moth; and <u>Monilinia fructigena</u> Honey, the leaf scorch fungus.

- (a) General requirements. (1) The national plant protection organization (NPPO) of Spain must provide a bilateral workplan to APHIS that details the activities that the NPPO of Spain will, subject to APHIS' approval of the workplan, carry out to meet the requirements of this section. APHIS will be directly involved with the NPPO of Spain in monitoring and auditing implementation of the systems approach. The NPPO of Spain must also enter into a trust fund agreement with APHIS in accordance with § 319.56-6.
- (2) All places of production and packinghouses that participate in the export program must be registered with the NPPO of Spain.
- (3) The fruit must be grown at places of production that meet the requirements of this section
- (4) The fruit must be packed for export to the United States in a packinghouse that meets the requirements of paragraph (i) of this section. The place of production where the apricots were grown must remain identifiable when the fruit leaves the grove, at the packinghouse, and throughout the export process. Safeguarding in accordance with paragraph (h) of this section must be maintained at all times during the movement of the apricot fruit to the United States and must be intact upon arrival of the apricot fruit in the United States.
- (b) <u>Commercial consignments</u>. Apricots from continental Spain may be imported to the United States in commercial consignments only.
- (c) Monitoring and oversight. (1) The NPPO of Spain, or an authorized person designated in the workplan, must visit and inspect places of production starting at least 1 month (30 days) before harvest and continuing until the end of the shipping season to verify that growers are complying with the requirements of this section and to follow pest control guidelines, when necessary, to reduce quarantine pest populations. The NPPO of Spain must

certify that exporting places of production have fruit fly and moth trapping programs and follow control guidelines, when necessary, to reduce regulated pest populations. Any personnel conducting trapping and pest surveys must be accredited and supervised by the NPPO of Spain.

APHIS may monitor the places of production if necessary.

- (2) In addition to conducting fruit inspections at the packinghouses, the NPPO of Spain must monitor packinghouse operations to verify that the packinghouses are complying with the requirements of this section.
- (3) If the NPPO of Spain finds that a place of production or packinghouse is not complying with the requirements of this section, no fruit from the place of production or packinghouse will be eligible for export to the United States until APHIS and the NPPO of Spain conduct an investigation and implement appropriate remedial actions.
- (4) The NPPO of Spain must retain all forms and documents related to export program activities in places of production and packinghouses for at least 1 year and, as requested, provide them to APHIS for review.
- (d) <u>Grove sanitation</u>. Fruit that has fallen from the trees at each place of production must be removed and destroyed weekly.
- (e) <u>Fungi</u>. During the growing season, the NPPO of Spain must conduct inspections at intervals specified in the workplan in the place of production for signs of <u>A</u>. <u>erythrostoma</u> and <u>M</u>. <u>fructigena</u> until harvest is completed. Infected leaves must be removed from places of production to reduce the inoculum potential. Upon detection of these fungal diseases, the NPPO of Spain must notify APHIS, which may prohibit the importation into the United States of apricots from the production site for the season.

- (f) <u>C</u>. <u>funebrana</u>. The NPPO of Spain must use one of the following two mitigation measures to address the risk potential posed by <u>C</u>. <u>funebrana</u>.
- (1) <u>Pest-free area</u>. Under this mitigation measure, apricots must originate from an area designated as free of <u>C</u>. <u>funebrana</u> in accordance with § 319.56-5.
- (2) Area of low pest prevalence and pest management. Under this mitigation measure, the NPPO of Spain must visit and visually inspect registered places of production during the growing season and harvest period for signs of C. funebrana to demonstrate that the places of production have a low prevalence of C. funebrana and to verify that the growers are complying with the requirements of this paragraph. The NPPO of Spain must also sample and visually inspect a quantity of fruit specified in the workplan. Trapping must also be conducted in the places of production to demonstrate that the places of production have a low prevalence of C. funebrana. If the prevalence of any life stage of C. funebrana rises above levels specified in the bilateral workplan, remedial measures approved jointly by APHIS and the NPPO of Spain must be implemented. The NPPO of Spain must keep records of the placement of traps, trap visits, trap counts, and treatments for each registered place of production and make the records available to APHIS upon request.
- (g) <u>C</u>. capitata. (1) Trapping must be conducted in the places of production to demonstrate that those places of production have a low prevalence of <u>C</u>. capitata. Specific trapping requirements are included in the bilateral workplan. If the prevalence rises above levels specified in the bilateral workplan, remedial measures approved jointly by APHIS and the NPPO of Spain must be implemented. The NPPO of Spain must keep records of the placement of traps, trap visits, trap counts, and treatments for each registered place of production and make the records available to APHIS upon request.

- (2) All apricots for export from continental Spain to the United States must be treated for C. capitata in accordance with part 305 of this chapter.
- (h) <u>Post-harvest procedures</u>. The apricots must be safeguarded by a pest-proof screen, plastic tarpaulin, or by some other pest-proof barrier while in transit to the packinghouse and while awaiting packing. They must be packed within 24 hours of harvest into pest-proof cartons or containers or covered with pest-proof mesh or a plastic tarpaulin for transport to the United States. These safeguards must remain intact until arrival of the consignment in the United States.
- (i) <u>Packinghouse requirements</u>. Packing of apricots for export to the United States must be conducted within a packinghouse registered and approved by the NPPO of Spain.

 Packinghouses in which apricots are packed for export to the United States must be able to exclude quarantine pests. All openings to the outside of the packinghouse must be covered by screening with openings of not more than 1.6 mm or by some other barrier that prevents pests from entering. The packinghouse must have double self-closing doors at the entrance to the facility and at the interior entrance to the area where the apricots are to be packed. During the time registered packinghouses are in use for packing apricots for export to the United States in accordance with the requirements of this section, packing lines must be cleared of all other articles and plant debris prior to packing such apricots, and such apricots must be stored in a room separate from any other fruits or plant articles while the apricots are at the packinghouse.
- (j) <u>Phytosanitary inspection</u>. (1) A biometric sample of apricot fruit jointly agreed upon by APHIS and the NPPO of Spain must be inspected in Spain by the NPPO of Spain following post-harvest processing. The sample must be visually inspected for the quarantine pests

 <u>A. erythrostoma, C. funebrana, and M. fructigena</u>. A portion of the fruit must be cut open and

inspected for C. capitata. If any of these quarantine pests are found, the entire consignment of

apricot fruit will be prohibited from importation into the United States.

(2) Fruit presented for inspection at a U.S. port of entry must be identified in the shipping

documents accompanying each lot of fruit that specify the place of production in which the fruit

was produced and the packinghouse in which the fruit was processed. This identification must

be maintained until the fruit is released for entry into the United States.

(k) Phytosanitary certificate. Each consignment of apricot fruit must be accompanied by

a phytosanitary certificate issued by the NPPO of Spain that states that the fruit has been treated

for C. capitata in accordance with 7 CFR part 305 and includes an additional declaration that the

fruit in the consignment was inspected and found free from A. erythrostoma, C. capitata,

C. funebrana, and M. fructigena.

(Approved by the Office of Management and Budget under control number 0579-0402)

Done in Washington, DC, this 23rd day of December 2013.

Kevin Shea

Administrator, Animal and Plant Health Inspection Service.

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